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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,286	07/03/2006	**Sunil Shaunak**	POLYT 9866 WO - US	2614

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EXAMINER	
LAU, JONATHAN S	
ART UNIT	**PAPER NUMBER**
1623	

NOTIFICATION DATE	DELIVERY MODE
08/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/585,286	SHAUNAK ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *78-97* is/are pending in the application.

4a) Of the above claim(s) *91 and 94-97* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *78-90,92 and 93* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 March 2009* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5 pgs / 4 Jul 2006, 14 Sep 2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is the national stage entry of PCT/GB05/00039, filed 7 Jan 2005; and claims benefit of foreign priority document UNITED KINGDOM 0400264.8, filed 7 Jan 2004; this foreign priority document is in English.

Claims 78-97 are pending in the current application. Claims 94-97, drawn to non-elected inventions, are withdrawn. Claim 91, drawn to non-elected species, are withdrawn. Claims 78-90, 92 and 93 are examined on the merits herein.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 25 Mar 2010 is acknowledged. The traversal is on the ground(s) that GB 229070 teaches an amphotericin B bonded by an ester linkage to an acrylic or methacrylic polymer. This is not found persuasive because the specification at page 10, lines 8-15 also defines the term “complex" to include that “Although a complex according to the present invention predominantly involves non-covalent association between the components, there may nevertheless be some covalent bonding.” One of ordinary skill in the art would understand that due to the proximity of the covalently bound amphotericin B to the acrylic or methacrylic polymer the amphotericin B would necessarily also non-covalently interact by one or more of ionic, electrostatic and van der Waals forces with the acrylic or methacrylic polymer. Therefore the technical feature taught by GB 229070 is encompassed within the instant invention as claimed.

The requirement is still deemed proper and is therefore made FINAL.

Claims 94-97 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 25 Mar 2010.

Applicant's election with traverse of species 1 of a polymer comprising unit (I), species 2 of amphotericin B, species 3 of daunorubicin, and species 4 of tuberculin antigen in the reply filed on 25 Mar 2010 is acknowledged. The traversal is on the ground(s) that the three genera are members of a single Markush group and the species are members of an art-recognized class. This is not found persuasive because there is a serious search and examination burden for the species having different chemical structure and pharamacological activities as a result of different chemical structures, and the current record does not show the species to be obvious variants.

The requirement is still deemed proper and is therefore made FINAL.

Claim 91 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the election of species requirement in the reply filed on 25 Mar 2010.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 78-88 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 78 recites "polymer comprising units derived from an acrylic acid". Claims 79-88 depend from claim 78 and incorporate all limitations therein. This phrase renders the claims indefinite because it is unclear what monomeric units are meant by the phrase "units derived from an acrylic acid". The ordinary definition of a derivative in the chemical arts is "A compound obtained from another" (definition 5 of derivative, Oxford English Dictionary, cited in PTO-892). Therefore it is unclear if the units derived from an acrylic acid encompasses, for example, either hydroxypropyl methacrylamide or vinylpyrrolidine. Therefore one of ordinary skill in the art would not be readily apprised of the metes and bounds of the invention as claimed.

Claim 83 recites the limitation "the pharmacologically active substance" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Claim 83 depends from claim 78, and claim 78 recites a substance that has a pharmacological activity against a pathogenic organism, a substance having pharmacological activity against a cancer, and an antigen or immunogen that may be pharmacologically active. It is unclear which of these substances recited in claim 78 is recited in claim 83. For the purpose of facilitating prosecution, claim 83 is interpreted as being drawn to the

substance that has a pharmacological activity against a pathogenic organism based on the Applicant's reply filed on 25 Mar 2010.

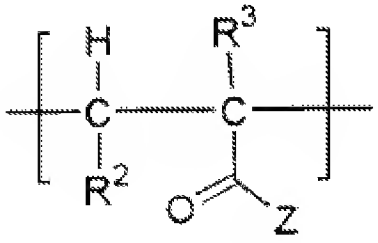
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 78-88 and 92 are rejected under 35 U.S.C. 102(b) as being anticipated by Brocchini et al. (WIPO Publication WO 01/18080 A1, published 15 Mar 2001, provided by Applicant in IDS mailed 03 July 2006).

Brocchini et al. discloses an acrylic acid polymer drug conjugate wherein the polymer has a polydispersity of preferably less than 1.2 and a molecular weight of less than 100,000 (abstract), meeting limitations of instant claim 86. Brocchini et al. discloses the embodiment within the polymer comprises the unit (II)



(II)

wherein R^2 includes hydrogen or C_1-C_{18} alkyl, R^3 includes hydrogen and Z includes the groups OR^7 where R^7 includes hydrogen (page 18 lines 20-30 and page 19, lines 1-5). Brocchini et al. discloses the drug is preferably an agent such as daunomycin (page 19, lines 25-30), meeting limitations of

the substance having pharmacological activity against a cancer of instant claims 78-90, 92 and 93. Brocchini et al. discloses the polymer having a molecular weight of less than 100,000 and more preferably 25,000-40,000 (page 18, lines 15-20), meeting limitations of instant claims 87 and 88. Brocchini et al. discloses the acrylic acid polymer drug conjugate as a covalently bonded conjugate. However, as recited above, the specification at page 10, lines 8-15 also defines the term “complex" to include that “Although a complex according to the present invention predominantly involves non-covalent association between the components, there may nevertheless be some covalent bonding.” and one of ordinary skill in the art would understand that due to the proximity of the covalently bound drug to the acrylic or methacrylic polymer the drug would necessarily also non-covalently interact by one or more of ionic, electrostatic and van der Waals forces with the acrylic or methacrylic polymer, therefore the “complex” as recited in the instant claims encompasses the covalently bonded conjugate. Brocchini et al. discloses the polymer drug conjugate in a pharmaceutical composition (page 17, lines 5-10), such as with a pharmaceutically acceptable excipient (page 50, lines 20-25), or a carrier, meeting limitations of instant claim 92. Instant claims 79-83 recite further limitations of the pathogenic organism and instant claims 84-85 recite limitations of the antigen or immunogen, however the claims do not require the compound to be a substance having activity against a pathogenic organism or an antigen or immunogen, therefore daunomycin, or substance having pharmacological activity against a cancer, meets the limitations of instant claims 79-82 and 84-85.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

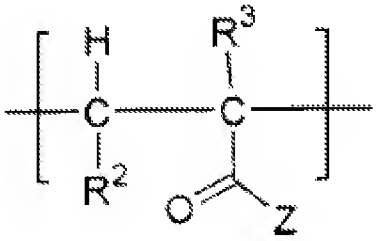
This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 78-90 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini et al. (WIPO Publication WO 01/18080 A1, published 15 Mar 2001, provided by Applicant in IDS mailed 03 July 2006).

Brocchini et al. discloses as above.

Brocchini et al. does not specifically disclose the polymer is poly(methacrylic acid) (instant claim 89). Brocchini et al. does not specifically disclose the polymer comprises unit (I) according to the elected species (instant claim 90).

Brocchini et al. teaches the embodiment within the polymer comprises the unit



(II)

(II) wherein R^2 includes hydrogen or C_1-C_{18} alkyl, R^3 includes hydrogen and Z includes the groups OR^7 where R^7 includes hydrogen (page 18 lines 20-30 and page 19, lines 1-5). Brocchini et al. teaches preferably R^2 is selected from a group including hydrogen and C1-C6 alkyl and most preferably R^2 is hydrogen and R^3 is hydrogen or methyl (page 19, lines 10-15).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teaching of Brocchini et al. to practice the invention wherein the polymer is poly(methacrylic acid). One of ordinary skill in the art would have been motivated to select the teaching of Brocchini et al. with a reasonable expectation of success because Brocchini et al. teaches guidance for selecting the preferred R groups.

Claims 78-90 and 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini et al. (WIPO Publication WO 01/18080 A1, published 15 Mar 2001, provided by Applicant in IDS mailed 03 July 2006) and in view of Kuzuya et al. (US Patent 5,889,078, issued 30 Mar 1999, provided by Applicant in IDS mailed 03 July 2006). Junior et al. (WIPO Publication WO 03/039435, published 15 Mar 2003, provided by Applicant in IDS mailed 03 July 2006) provides evidence of inherency.

Brocchini et al. teaches as above.

Brocchini et al. does not specifically teach the elected species of a substance that has a pharmacological activity against a pathogenic organism of amphotericin B (instant claims 79-83).

Kuzuya et al. teaches a polymer of acrylic acid or methacrylic acid combined with a drug (abstract). Kuzuya et al. teaches drugs that are compatible with the acrylic acid or methacrylic acid polymer include amphotericin B (column 2, line 30). Junior provides evidence of inherency that amphotericin B (Junior et al. abstract) can be used to be treat leishmaniasis (Junior et al. page 11, lines 10-20)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Brocchini et al. in view of Kuzuya et al. It would have been obvious to one of ordinary skill in the art to substitute the drug taught by Brocchini et al. for the drug amphotericin B taught by Kuzuya et al. with a reasonable expectation of success because both Brocchini et al. and Kuzuya et al. teach acrylic acid or methacrylic acid polymer drug conjugates. Instant claims 84-85 recite limitations of the antigen or immunogen, however the claims do not require the compound to be an antigen or immunogen, therefore amphotericin B renders obvious the limitations of instant claims 84-85.

Claims 78-90, 92 and 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini et al. (WIPO Publication WO 01/18080 A1, published 15 Mar 2001, provided by Applicant in IDS mailed 03 July 2006) and in view of Norimov et al. (Bulletin of Experimental Biology and Medicine, 1991, 111(2), p216-218, cited in

PTO-892) and Kreuter et al. (Infection and Immunity, 1978, 19(2), p667-675, provided by Applicant in IDS mailed 03 July 2006).

Brocchini et al. teaches as above.

Brocchini et al. does not specifically teach the elected species of antigen tuberculin (instant claims 84 and 85). Brocchini et al. does not specifically teach the composition further comprising a delivery system adjuvant (instant claim 93).

Norimov et al. teaches immunogenic complexes of polyacrylic acid and tuberculosis antigens (page 216, paragraph 4), or tuberculin, are previously known in the art. Norimov et al. teaches it is routine in the art to combine immunogenic compounds with adjuvants such as Freund's adjuvants (page 217, paragraph 6), or a delivery system adjuvant.

Kreuter et al. teaches the ordinary level of skill in the art with regard to the immunological adjuvant effectivity of polyacrylic acid (page 667, abstract). Kreuter et al. teaches most frequently used adjuvants are water-in-oil emulsions such as Freund's adjuvants and aluminum compounds (page 667, left column, paragraph 2).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine Brocchini et al. in view of Norimov et al. and Kreuter et al. One of ordinary skill in the art would have been motivated to combine Brocchini et al. in view of Norimov et al. with a reasonable expectation of success because Brocchini et al. teaches the polymer used in the broader field of polymer therapeutics (page 2, lines 10-20) and Norimov et al. teaches immunogenic complexes of polyacrylic acid and tuberculin are known in the art. One of ordinary skill in the art would have been

motivated to combine Brocchini et al. in view of Norimov et al. and Kreuter et al. to include a delivery system adjuvant because Norimov et al. and Kreuter et al. teach such adjuvants are frequently used. Instant claims 79-83 recite further limitations of the pathogenic organism, however the claims do not require the compound to be a substance having activity against a pathogenic organism, therefore the antigen tuberculin renders obvious the limitations of instant claims 79-82.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 78-90 and 92 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 5, 6, 8, 12, 35, 43, 47, 48 and 49 of U.S. Patent No. 6,803,438. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent No. 6,803,438 corresponds to Brocchini et al. (WIPO Publication WO 01/18080 A1) as recited above and claims 1, 3, 4, 5, 6, 8, 12, 35, 43, 47, 48 and 49 of U.S. Patent No. 6,803,438 are drawn to the (meth)acrylic acid polymer conjugate of doxorubicin, daunomycin or paclaxitel (*sic*), and the specification provides guidance as recited above.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-

3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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